

March 12, 2003

Examiner Michael Cygan
Art Unit 2856
United States Patent and Trademark Office
Fax No. 703-746-9214

Re: Application No. 09/729,118

Attached is a copy of our January 24 Amendment after Final.

We look forward to meeting with you and to receiving your comments on our Amendment after Final on March 13 (tomorrow), at 10 AM.

In the meantime, please let us know if you have any questions or other comments.

Philip D. Freedman
Philip D. Freedman PC
6000 Wescott Hills Way
Alexandria, Virginia 22315-4747
(703) 313-0171
Fax: (703) 313-9322
Email: tekесq@tekесq.com

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Application No. 09/665,767

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RESPONSE UNDER 37 CFR §1.116
EXPEDITED PROCEDURE
EXAMINING GROUP 1712

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

CARNAHAN et al.

Application No.: 09/665,767

Group Art Unit: 2856

Examiner: Michael Cygan

Filed: September 20, 2000

For: METHOD AND APPARATUS FOR RAPID DETERMINATION OF
POLYMER MOLECULAR WEIGHT

AMENDMENT AFTER FINAL REJECTION UNDER 37 C.F.R. §1.116

Assistant Commissioner for Patents
Box AF
Washington, D. C. 20231

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Sir:

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In response to the Final Rejection dated November 22, 2002, please amend the
above-identified application as follows:

IN THE CLAIMS:

Please rewrite claims 1, 28 and 31 as follows:

1. A method for the determination of polymer molecular weight,
comprising:injecting a known volume of an analytical sample comprising a polymer
reaction product of a diphenyl carbonate and a dihydric phenol into a flow analysis
system comprising an on line single path through (1) a chromatographic column, (2) a
sequential concentration detector, and (3) a sequential waste reservoir, and an off-line
molar mass detector after the concentration detector and non-sequential with the
chromatographic column (1), concentration detector (2) and waste reservoir (3);

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effecting a minimally dispersive separation of the analytical sample with the chromatographic column to yield a high molecular weight fraction;

determining a polymer concentration in the high molecular weight fraction using the concentration detector;

determining off-line the molar mass using the molar mass detector on a diverted high molecular weight fraction; and

deriving an average molecular weight from the polymer concentration and the molar mass;

wherein the total analysis time is not greater than about 5 minutes per sample.

28. A method for the determination of polymer molecular weight, comprising:

providing a sample array comprising a plurality of spatially differentiated sites, each site comprising a polymer resin reaction product of a diphenyl carbonate and bisphenol A;

preparing an analytical sample for each spatially differentiated site by dissolving the polymer resin reaction product in a suitable solvent;

injecting a known amount of each analytical sample into a flow analysis system comprising sequentially a chromatographic column, a concentration detector, and a waste reservoir, and a molar mass detector off-line from the sequential chromatographic column, concentration detector and waste reservoir;

effecting a minimally dispersive separation of each analytical sample with the chromatographic column to yield a high molecular weight fraction comprising polycarbonate oligomers and polymers comprising at least two bisphenol A units, said fraction being substantially free of monomers;

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determining a polymer concentration in the high molecular weight fraction of each analytical sample using the concentration detector;

diverting a portion of each analytical sample to the molar mass detector and disposing the remainder of each analytical sample to the waste reservoir; and

determining the molar mass in the high molecular weight fraction of the diverted portion of each analytical sample using the molar mass detector; and

deriving an average molecular weight for each analytical sample based on the polymer concentration and the molar mass;

wherein the total analysis time is not greater than about 5 minutes per sample.

31. A system for the determination of polymer average molecular weight, comprising:

a solvent delivery system;

an autoinjector for injecting a known volume of an analytical sample comprising a polymer reaction product of a diphenyl carbonate and a dihydric phenol;

a chromatographic column for effecting a minimally dispersive separation of the analytical sample to yield a high molecular weight fraction substantially free of monomers;

an in-line concentration detector for determining a polymer concentration in the high molecular weight fraction; and

an in-line waste reservoir in sequence with the chromatographic column and in-line concentration detector; and

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a molar mass detector off-line from the sequence of chromatographic column, concentration detector and waste reservoir, for determining the molar mass in the high molecular weight fraction;

wherein the system's total analysis time is not greater than about 5 minutes per sample.

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REMARKS

The amendments are based on the specification page 10, lines 17 to 29 and drawing FIG. 2. The amendments to claim 31 also correct two spelling errors.

Claims 1, 4 to 8, 10 to 21, 23 to 29, 31, 34 to 36 and 38 to 43 are pending. The November 22, 2002 Final Rejection rejected claims 1, 4 to 8, 10, 11, 18, 19, 21, 23, 24, 26 to 29, 31 and 34 to 36 under 35 U.S.C. §103(a) over Miroslav and Allcock and rejected claims 12 to 17, 20, 25 and 38 to 43 under 35 U.S.C. §103(a) over Miroslav, Allcock and Nielsen et al. Reconsideration is respectfully requested for the following reasons:

The invention relates to a method for speedy determination of the molecular weight of a polymer reaction product of a diphenyl carbonate and a dihydric phenol. The specification points out that the reaction product of this reaction is a complex mixture of:

"reactants (e.g., monomers), catalysts, pH buffers, and non-polymeric products, in addition to oligomeric and polymeric products of polymerization. When the polymer comprises an aromatic polycarbonate, the reaction mixture may comprise, for example, the reactants diphenyl carbonate and bisphenol A, the product phenol, and a catalyst, in addition to polycarbonate oligomers and polymers.

Specification page 6, lines 5 to 11.

Additionally, the specification points out:

Alternatively, the molar mass determination may be conducted off-line after the concentration determination by diverting the high molecular weight fraction to a molar mass detector that has a cell capable of containing and effecting rapid mixing of the entire HMWF that is separable from the main flow of pumped solvent. The off-line embodiment permits more accurate determination of the average molecular weight and simplifies the calculation of average molecular weight. This is then equivalent to determination with zero dispersion or separation of the polymer but permits elimination of interfering low molecular weight substances. This configuration is shown in Figure 2. (Emphasis added.)

Specification page 10, lines 22 to 29.

Claim 1 claims a method for determination of polymer molecular weight comprising a step of "determining off-line... molecular mass... on a diverted high molecular weight fraction" in an "off-line molar mass detector after the concentration detector and non-sequential with the chromatographic column (1), concentration detector (2) and waste reservoir (3)." Claim 28 claims "diverting a portion of each analytical sample to the molar mass detector and disposing the remainder of each analytical sample to the waste reservoir; and determining the molar mass in the high molecular weight fraction of the diverted portion of each analytical sample using the molar mass detector." Claim 31 claims a system for the determination of polymer average molecular weight comprising "a molar mass detector off-line from the sequence of chromatographic column, concentration detector and waste reservoir, for determining the molar mass in the high molecular weight fraction."

I. THE REFERENCES DO NOT TEACH OR SUGGEST "OFF-LINE" AS DEFINED BY THE AMENDED CLAIMS

Miroslav, Allcock and Nielsen et al. do not teach or suggest "off-line" molar mass detection. The October 21 Office Action argued that with respect to claims 22 and 33 ("off-line" claims now cancelled in favor of independent amended claims 1 and 31) that "the examiner takes Official Notice of the equivalence of offline and online techniques in the analysis art...." Applicants traversed this assertion. MPEP 2144.03 provides that "[i]f the applicant traverses such an assertion [Official Notice] the examiner should cite a reference in support of his or her position."

In the Final Rejection, the PTO argued that the traverse to the "Official Notice" was not timely. The Patent Office made this assertion in its November 14, 2001 Office Action but the rejections of that Office Action were based on references that were overcome by Applicants' February 8, 2002 Declaration establishing invention prior to the effective date of the references. In July 2002, the PTO provided a copy of a provisional application teaching that established an earlier priority date for the November 14, 2001 references. The PTO iterated its assertion for the first time thereafter, only in its October 21, 2002 Office Action. To that date, the assertion was not an issue. To that date, the

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only issue was whether Applicants' Declaration established invention prior to the references. The October 21 Office Action was the first time the assertion was effectively raised as an issue. The Applicants timely traversed the assertion in their Supplemental Amendment filed the same date as the PTO's next October 21 Office Action.

While the Final Rejection argues that the traversal of "Official Notice" was untimely, the Final Rejection also cites Drukier allegedly in support of "off-line" obviousness. But Drukier teaches a combined HPLC separation and detection off-line to a main effluent producing procedure. This is opposite the claimed off-line molar mass detection of a fraction from an on-line chromatographic column.

Miroslav, Allcock, Nielsen et al. and Drukier fail to establish a *prima facie* case of obviousness. "*A prima facie* case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art...." *In re Rijckaert*, 28 USPQ2d 1955, 1956 (Fed. Cir. 1992). Miroslav, Allcock, Nielsen et al. and Drukier do not teach or suggest a step of "determining... molecular mass... on a diverted high molecular weight fraction" in a molar mass non-sequential with a sequential chromatographic column (1), concentration detector (2) and waste reservoir (3) (claims 1, 4 to 21 and 23 to 27). Miroslav, Allcock, Nielsen et al. and Drukier do not teach or suggest "diverting a portion of each analytical sample to the molar mass detector and ... determining the molar mass in the high molecular weight fraction of the diverted portion... using the molar mass detector" (claim 28 and 29). Miroslav, Allcock, Nielsen et al. and Drukier do not teach or suggest a system... comprising "a molar mass detector off-line from the sequence of column concentration detector and waste reservoir..." (claims 31 and 34 to 36).

"Off-line" molar mass detection that "permits more accurate determination of the average molecular weight and simplifies the calculation of average molecular weight" would not have been obvious in view of the Miroslav, Allcock and Nielsen et al. on-line detection that does not improve accuracy or simplify the determination of average molecular weight. Molar mass detection "off-line" to a separation would not have been obvious in view of the Drukier teaching of an on-line or off-line separation.

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"If examination... does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent." *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). "When the reference cited by the examiner fail to establish a *prima facie* case of obviousness, the rejection is improper and will be overturned." *In re Deuel*, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995). The references do not establish a *prima facie* of obviousness. The rejections of claims 1, 4 to 8, 10, 11, 18, 19, 21, 23, 24, 26 to 29, 31 and 34 to 36 under 35 U.S.C. §103(a) over Miroslav and Allcock and claims 12 to 17, 20, 25 and 38 to 43 under 35 U.S.C. §103(a) over Miroslav, Allcock and Nielsen et al. should be withdrawn.

II. ALLCOCK IS IMPROPERLY COMBINED

Miroslav and Nielsen et al. fail to teach or suggest a method for determination of polymer molecular weight of a 'polymer reaction product of a diphenyl carbonate and a dihydric phenol.' The Office Action states:

Allcock teaches that polycarbonates "of particular importance" are formed by reaction of bisphenol A (a dihydric phenol with the chemical formula of 2,2-bis(4-hydroxyphenyl propane) and diphenyl carbonate, (and inherently an appropriate solvent) see page 29.

Final Rejection pages 4 to 5..

The Final Rejection concludes:

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a product of a polymer reaction between a diphenyl carbonate and a dihydric phenol as taught by Allcock in the invention of Miroslav as a sample for analysis in order to provide advantageous use of the invention of Miroslav, since Allcock teaches that such a product is "of particular importance". [sic] and Miroslav states that his invention is to be used with polymerization reaction product mixtures having commercial importance.

Final Rejection page 4.

This is an improper "conclusionary" statement unsupported by "the reasoned logic required by *In re Lee*, 61 USPQ 2d 1430, 1434, 277 F.3d 1338, ____ (Fed. Cir. 2002).

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In re Lee holds that the PTO "must not only assure that... requisite findings are made, based on evidence of record, but must also explain the reasoning by which the findings are deemed to support the agency's conclusion [to combine references]." *In re Lee*, 61 USPQ 2d 1430, 1434, 277 F.3d 1338, ____ (Fed. Cir. 2002).

The chemical arts are unpredictable. As the court stated in *In re Marzocchi*, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971):

[T]n the field of chemistry generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim. This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles. Most often, additional factors, such as the teachings in pertinent references, will be available to substantiate any doubts that the asserted scope of objective enablement is in fact commensurate with the scope of protection sought and to support any demands based thereon for proof. [Footnote omitted.]

That Allcock discloses that diphenyl carbonate and dihydric phenol products are important is not a scientific basis that would have led one skilled in the unpredictable polymer art to conduct the Miroslav analytical process on a polymer revealed by Allcock.

An economic "commercially important" basis is not the reasoned logic required by *In re Lee*. A teaching of application to "polymer samples" is not a teaching to one skilled in the art of application to the particular chemical reaction product of a bisphenol and a diphenyl carbonate.

For this additional reason, the rejections should be withdrawn.

III. THE REFERENCES DONOT TEACH OR SUGGEST A MINIMALLY DISPERSIVE SEPARATION AS DEFINED BY SPPLICANTS' SPECIFICATION

Additionally, claim 28 claims a step of effecting a minimally dispersive separation to yield a high molecular weight fraction "comprising polycarbonate oligomers and polymers comprising at least two bisphenol A units...." The specification page 8, lines 8 to 29 states:

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A minimally dispersive separation is one that rapidly but substantially separates a high molecular weight fraction (HMWF) from a low molecular weight fraction (LMWF). The high molecular weight fraction is defined herein as comprising all oligomeric and polymeric products having at least two monomer units of at least one monomer. For example, the high molecular weight fraction of a sample comprising polycarbonate would comprise polycarbonate oligomers and polymers comprising at least two bisphenol A units.... In order to enable the fastest possible analysis time, it is preferred that the minimally dispersive separation create the least possible dispersion of the HMWF while maintaining its separation from the LMWF.

Miroslav, Allcock and Drukier et al. do not teach or suggest a "minimally dispersive separation... to yield a high molecular weight fraction... comprising polycarbonate oligomers and polymers comprising at least two bisphenol A units."

The Final Rejection argued that the claimed "minimally dispersive separation" is taught at column 21, line 62 through column 22, line 2 (of Miroslav). This is incorrect. The Miroslav separation results in a "polymer component(s)" fraction. Claim 28 and its dependent claims are limited to a separation that yields "oligomers and polymers" (emphasis added). Otherwise, the separation is not "minimally dispersive." A minimally dispersive separation that enables the "fastest possible analysis" would not have been obvious in view of the Miroslav and Allcock references non-minimally dispersive separation that does not provide the "fastest possible analysis." Claim 29 depends from claim 28. The rejection of claims 28 and 29 should be withdrawn.

IV. THE PTO SHOULD RESPOND TO APPLICANTS' ARGUMENTS

Applicants previously filed a REQUEST FOR RECONSIDERATION AFTER FINAL REJECTION UNDER 37 C.F.R. §1.116. In that REQUEST, Applicants argued that (1) Drukier teaches a combined HPLC separation and detection off-line to a main effluent producing procedure, which is the opposite of Applicants claimed off-line molar mass detector and that (2) Applicants timely traversed the PTO's "Official Notice" assertion. Subsequently, the PTO issued a January 2 Advisory Action stating only that "THE REPLY FILED 09 December 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE."

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The Manual of Patent Examining Procedure provides "Completeness and Clarity of Examiner's Action," "[t]he examiner must address all arguments which have not already been responded to in the statement of the rejection" (MPEP 707.07); "Answer All Material Traversed" "Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it" (MPEP 707.07(f)); and "Amendments After Final Rejection or Action, Procedure Followed" "Advisory Action form PTOL-303 should be used to acknowledge receipt of a reply from applicant after final rejection where such reply is prior to filing of an appeal brief and does not place the application in condition for allowance. This form has been devised to advise applicant of the disposition of the proposed amendments to the claims and of *the effect of any argument* or affidavit not placing the application in condition for allowance or which could not be made allowable by a telephone call to clear up minor matters" (MPEP 714.13, emphasis added). The Advisory Action failed to respond to Applicants' arguments (1) and (2). The PTO is respectfully requested to allow the claims or to address Applicants' arguments (1) and (2) and the *prima facie* argument, non-predictability of chemical reactions argument and "minimally dispersive separation" argument of this Amendment.

Additionally, the PTO has failed to properly make provisional application 60080652 and Petro 6,260,407 of record. Applicants have argued that so long as these references are not of record, the PTO has failed to overcome Applicants' Declaration establishing invention prior to the effective date of the Miroslav reference.

The MPEP 2271 states:

In making the final rejection, all outstanding grounds of rejection of record should be carefully reviewed and any grounds or rejection relied on should be reiterated. The grounds of rejection must (in the final rejection) be clearly developed to such an extent that the patent owner may readily judge the advisability of an appeal.... [T]he final rejection... should include a rebuttal of any arguments raised in the patent owner's response. (Emphasis added.)

The PTO has not developed the grounds for rejection on Miroslav so long as provisional application 60080652 and Petro 6,260,407 are not of record.

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V. CONCLUSION

The above amendments should place this application in condition for allowance. The amendments add no new issues. The amendments only clarify the "off-line" method and system. Thus, entry of the amendments is requested under 37 CFR §1.116. In the alternative, if the application is not allowed, applicants respectfully request the PTO to withdraw the final rejection and properly make provisional application 60080652 and Petro 6,260,407 of record and reissue another office action addressing applicants' arguments.

In view of the foregoing remarks, reconsideration and allowance of claims 1, 4 to 8, 10 to 21, 23 to 29, 31, 34 to 36 and 38 to 43 are respectfully requested.

Should the Examiner believe that any further action is necessary in order to place this application in condition for allowance, he is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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Philip D. Freedman
Reg. No. 24,163
Philip D. Freedman PC
Customer Number 25101
6000 Wescott Hills Way
Alexandria, Virginia 22315-4747
(703) 313-0171
Fax: (703) 313-9322
Email: tekcsq@tekcsq.com

Alexandria, Virginia
_____, 2003

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Please rewrite claims 1, 28 and 31 as follows:

1. (three times amended) A method for the determination of polymer molecular weight, comprising:

injecting a known volume of an analytical sample comprising a polymer reaction product of a diphenyl carbonate and a dihydric phenol into a flow analysis system comprising an on line single path through (1) a chromatographic column, (2) [and] a sequential concentration detector, and (3) a sequential waste reservoir, and an off-line molar mass detector after the concentration detector and non-sequential with the chromatographic column (1), concentration detector (2) and waste reservoir (3);

effecting a minimally dispersive separation of the analytical sample with the chromatographic column to yield a high molecular weight fraction;

determining a polymer concentration in the high molecular weight fraction using the concentration detector;

determining off-line the molar mass using the molar mass detector on a diverted high molecular weight fraction; and

deriving an average molecular weight from the polymer concentration and the molar mass;

wherein the total analysis time is not greater than about 5 minutes per sample.

28. (three times amended) A method for the determination of polymer molecular weight, comprising:

providing a sample array comprising a plurality of spatially differentiated sites, each site comprising a polymer resin reaction product of a diphenyl carbonate and bisphenol A;

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preparing an analytical sample for each spatially differentiated site by dissolving the polymer resin reaction product in a suitable solvent;

injecting a known amount of each analytical sample into a flow analysis system comprising sequentially a chromatographic column, a concentration detector, and a waste reservoir, and a molar mass detector off-line from the sequential chromatographic column, concentration detector and waste reservoir,

effecting a minimally dispersive separation of each analytical sample with the chromatographic column to yield a high molecular weight fraction comprising polycarbonate oligomers and polymers comprising at least two bisphenol A units, said fraction being substantially free of monomers;

determining a polymer concentration in the high molecular weight fraction of each analytical sample using the concentration detector;

diverting a portion of each analytical sample to the molar mass detector and disposing the remainder of each analytical sample to the waste reservoir; and

determining the molar mass in the high molecular weight fraction of the diverted portion of each analytical sample using the molar mass detector; and

deriving an average molecular weight for each analytical sample based on the polymer concentration and the molar mass;

wherein the total analysis time is not greater than about 5 minutes per sample.

31. (three times amended) A system for the determination of polymer average molecular weight, comprising:

a solvent delivery system;

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an autoinjector for injecting a known volume of an analytical sample comprising a polymer reaction product of a [diphenyl] diphenyl carbonate and a [hydroxyl] dihydric phenol;

a chromatographic column for effecting a minimally dispersive separation of the analytical sample to yield a high molecular weight fraction substantially free of monomers;

an in-line concentration detector for determining a polymer concentration in the high molecular weight fraction; and

an in-line waste reservoir in sequence with the chromatographic column
and in-line concentration detector; and

a molar mass detector off-line from the sequence of chromatographic column, [and] concentration detector and waste reservoir, for determining the molar mass in the high molecular weight fraction;

wherein the system's total analysis time is not greater than about 5 minutes per sample.

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